NOV 29 2004

K042890

510(k) Summary of Safety and Effectiveness

In accordance with the provisions of Section 4 of the Safe Medical Devices Act of 1990 and 21 CFR 807.92, the following summary is provided. Biosite requests that this document be maintained CONFIDENTIAL until such time that the product is cleared by the Food and Drug Administration via the 510(k) process and in accordance with the provisions of the Act.

A. Name and Address of Submitter

Company Name:	Biosite Incorporated
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Contact Person:	Jeffrey R. Dahlen, Ph.D.
Date Summary Prepared:	October 14, 2004

B. Product

Triage® D-Dimer Test

C. Predicate Devices

Triage® Profiler S.O.B. Panel (K040437)

D. Device Description and Intended Use

The Triage® D-Dimer Test is a fluorescence immunoassay to be used with the Triage® Meter Plus for the quantitative determination of cross-linked fibrin degradation products containing D-dimer in EDTA whole blood and plasma specimens. The test is used as an aid in the assessment and evaluation of patients suspected of having disseminated intravascular coagulation or thromboembolic events including pulmonary embolism.

D-dimer is a protein arising directly from the body's natural mechanism to break down blood clots. Elevated levels of D-dimer in a patient's blood are indicative of abnormal rates of increased clot burden. Published studies suggest that D-dimer can be useful in the evaluation of suspected pulmonary embolism (PE).

E. Summary of Comparison Data

A method comparison of D-dimer results was performed using 180 specimens throughout the measurable range of the test. A Passing-Bablok regression analysis of the results yielded a linear relationship with a slope of 0.999, an intercept of -85.89 and a correlation coefficient of 0.92. The analytical performance characteristics of the assay were equivalent to predicate methods.

F. Conclusion

In conclusion, these studies demonstrate the substantial equivalence of the Triage D-Dimer Test to existing products already marketed for detecting the presence and degree of intravascular coagulation and fibrinolysis. They further demonstrated the suitability of the product for laboratory and professional use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 29 2004

Mr. Jeffrey Dahlen
Director, Clinical & Regulatory Affairs
Biosite Inc.
11030 Roselle Street
San Diego, CA 92121

Re: k042890
Trade/Device Name: Triage D-Dimer Test
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/fibrin degradation product assay
Regulatory Class: Class II
Product Code: GHH, DAP
Dated: November 19, 2004
Received: November 22, 2004

Dear Mr. Dahlen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042890

Device Name: **Triage D-Dimer Test**

Indications For Use:

The Triage® D-Dimer Test is a fluorescence immunoassay to be used with the Triage® Meter Plus for the quantitative determination of cross-linked fibrin degradation products containing D-dimer in EDTA whole blood and plasma specimens. The test is used as an aid in the assessment and evaluation of patients suspected of having disseminated intravascular coagulation or thromboembolic events including pulmonary embolism.

Prescription Use ✓ AND/OR Over-The Counter Use _____
(Per 21 CFR 801.109) (Per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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